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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,783	09/23/2003	Miroslav Smriga	241244US0CONT	9560
22850	7590	12/01/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1612	PAPER NUMBER
			NOTIFICATION DATE 12/01/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/667,783	Applicant(s) SMRIGA ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 24-26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 14-23 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>22 Oct 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed August 14, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

NOTE: Applicant asserts based on the previous rejection, the Examiner has clearly and minimally withdrawn the election of species requirement mailed September 25, 2006, to at least the extent that the claims read on treating gastric ulcers. In response, the Examiner confirms this assertion. Prosecution has been extended to the species of Gastric Ulcers.

Claims

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "wherein at least one of said one or more additional amino acids is selected from the group consisting of arginine, glutamic acid and aspartic" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1-4, 6-10, 12, 14-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takagi et al. (US 3,988,466).

Takagi et al. disclose compositions to treat gastric lesions induced by anti-inflammatory agents comprising at least one amino acid. The amino acids include L-lysine, L-arginine, L-glutamic acid and their pharmaceutically acceptable salts (col. 1, lines 53-59). The compositions comprise at least 1 g of amino acid (col. 1, line 65-68), which encompasses claims 16-19 (this is based on the average weight of a person being 75 kg). The amino acids are prepared in a dosage form such as a compressed tablet. Additional ingredients include starch, gelatine, magnesium stearate and sugar (col. 2, lines 27-38), encompassing claims 22 and 23. The reference differs from the instant claims insofar as it does not disclose the gastric ulcers are stress induced or that lysine is used in combination with glutamic acid.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07.

Although the reference does not disclose the ulcers are stress induced, it would have been obvious to use the compositions comprising lysine to treat stress induced ulcers motivated by the desire to treat the ulcer with a composition disclosed by the art that treats gastric ulcers.

In regards to lysine and glutamic acid being in combination, the reference recites "at least one amino acid". It may be concluded that a combination of amino acids may

be used in the compositions. Therefore it would have been obvious to use a combination of lysine and glutamic acid or a combination of lysine, glutamic acid and arginine in the compositions of the reference because the reference discloses using combinations of amino acids.

2) Claims 1-4, 6-10, 12, 15-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niebes et al. (US 4,507,314) in view of Takagi et al. (US 3,988,466).

Niebes et al. disclose a composition for treating stress induced ulcers comprising L-lysine. The ulcers include gastric ulcers. The compositions may also include L-arginine and L-ornithine. Although the lysine is used mainly as a reaction product with catechin, it is also added alone in injectable compositions (see col. 6, lines 15-20). The reference differs from the instant claims insofar as it does not disclose that the compositions comprise glutamic acid.

The secondary reference, Takagi et al., is disclosed above. The reference differs from the instant claims insofar as it does not disclose the gastric ulcers are stress induced.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

It would have been obvious to one of ordinary skill in the art to have added glutamic acid and arginine to the compositions of the primary reference motivated by the desire to use components that have been disclosed in the art as being effective in blocking the progress of gastric ulcers.

3) Claims 1-10, 12, 14-23 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Krnjevic (US 4,405,610) in view of Takagi et al. (US 3,988,466).

Krnjevic disclose compositions for treating conditions such as gastric ulcers with compositions comprising lysine orotate (col. 1, lines 19-26). The drug was given to patients in a dose of 25 mg a day and was usually administered in tea or undiluted milk. When in liquid form, 1.5 ml of composition with a concentration of 3 mg/ml (0.3%) is administered per 0.25 kg of body weight (18 mg per kg per body) (see claim 1). The reference differs from the instant claims insofar as it does not disclose the gastric ulcers are stress induced.

The secondary reference, Takagi et al., is disclosed above. The reference differs from the instant claims insofar as it does not disclose the ulcers are stress induced.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

It would have been obvious to one of ordinary skill in the art to have added glutamic acid and arginine to the compositions of the primary reference motivated by the desire to use components that have been disclosed in the art as being effective in blocking the progress gastric ulcers.

Claims 1-10, 12, 14-23 and 30-32 are rejected.

Claims 24-26 and 28-29 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612